

Application No. 10/540,156
Amendment dated January 4, 2008
Reply to Office Action of September 4, 2007

Docket No.: 1422-0679PUS1

AMENDMENTS TO THE DRAWINGS

The attached sheet of drawings is a more clear copy of the Figure 16.

Attachment: One (1) Replacement sheet

REMARKS

Status of the Claims

Claims 12-20 are currently pending in the application. Claims 1-5, 9 and 10 stand rejected. Claims 1-11 have been cancelled. All amendments and cancellations are made without prejudice or disclaimer. New claims 12-20 are presented. No new matter has been added by way of the present amendments. Specifically, new claims 12-20 are supported generally by original claims 1-5, 9 and 10, now cancelled, and throughout the specification. New claim 12 is essentially a combination of previous claims 1 and 2 (now cancelled). Reconsideration is respectfully requested.

Objections to the Specification

The Examiner objects to the specification because it contains typographical errors. (See, Office Action of September 4, 2007, at page 2, hereinafter "Office Action"). Applicants have herein entered corrections to the specification as suggested by the Examiner. The amendment of the specification in no way introduces new matter into the specification. One of ordinary skill in the art would immediately know that the scientific name "*F. velutipes*" was misspelled and the correct spelling. Thus, entry thereof is respectfully requested.

Information Disclosure Statement

The Examiner states that the Information Disclosure Statement (IDS) filed on June 21, 2005 fails to comply with 37 C.F.R. § 1.98(a)(3) because the Examiner did not receive a concise explanation of the relevance of references JP-10-501137-A and JP-2001-514513-A. However,

Applicants filed an English language Search Report indicating the relevance of these references. Furthermore, Applicants have previously submitted a copy of each of the corresponding WO publications (in English) to the USPTO in the IDS of September 21, 2005. The publication WO 98/40471 corresponds to JP 2001-514513 and the publication WO 95/33836 corresponds to JP 10-501137. Should the Examiner not find these references in the record, the Examiner is invited to contact Applicants' representatives at the contact information given below to obtain a copy.

Thus, the Examiner is respectfully requested to initial and return a corresponding SB/08 form citing these two Japanese publications. A clean SB/08 form, corresponding to the IDS filed on June 21, 2005, as submitted herewith for the Examiner's convenience.

Objections to the Drawings

The Examiner states that new corrected drawings are required because Figure 16 is illegible. Submitted herewith is believed to be a more clear copy of Figure 16 for the Examiner's consideration. Should the attached more clear copy of Figure 16 still be insufficient, the Examiner is invited to contact Applicants' representatives at the contact information provided below to discuss the matter further.

Reconsideration and withdrawal of the objection to Figure 16 are respectfully requested.

Rejections Under 35 U.S.C. § 101

Claims 1-4 stand rejected under 35 U.S.C. § 101 because they allegedly are directed to non-statutory subject matter. (*See*, Office Action, at page 3). Claims 1-4 have been cancelled herein in favor of new claims 12-20, thus obviating the rejection as to these claims. However,

Applicants provide the following remarks concerning the rejection to the degree that the bases for the rejections may also apply to new claims 12-20.

The Examiner states that the claims read on products of nature and that they encompass enzymes naturally occurring in living organisms. Thus, the Examiner suggests that the claims be amended to recite "An isolated neutral phenol oxidase having the following properties," for example.

Applicants have cancelled claims 1-4 in favor of new claims 12-20. It is noted that new claims 12-20 recite the term "isolated" as suggested by the Examiner, thereby addressing the rejection under 35 U.S.C. § 101.

Rejections Under 35 U.S.C. § 112, First Paragraph

The Examiner states that claim 5 is rejected under 35 U.S.C. § 112, first paragraph, as lacking written description support in the specification because the specific strain recited in the claim has not been indicated in the specification as having been deposited under the Budapest Treaty. (See, Office Action, at pages 4-7). Claim 5 has been cancelled; however, new claim 20 generally corresponds to similar subject matter. Therefore, the comments below are addressed to new claim 20.

U.S. Patent No. 7,135,184, cited by the Examiner, below, also claims strain IFO 30601. A similar issue arose during the prosecution of that patent. The issue was addressed by making the appropriate assurances and statements, as follows:

The Examiner states that the strain IFO 30601 is not known to be available and in compliance with U.S. Rules of Deposit as governed by the Budapest Treaty. According to 37

C.F.R. §§ 1.808 and 1.809, it is sufficient to notify the Examiner, in writing, that such samples will be made available during the pendency of the present application upon request by proper parties determined to be entitled to such access by the Director under 37 C.F.R. § 1.14 and 35 U.S.C. § 122, and that once allowed, all such restrictions on access to the samples will be irrevocably removed.

Thus, Applicants hereby notify the Examiner that the biological materials disclosed by the present invention will be maintained for a period of at least 30 years and at least 5 years after the most recent request for the furnishing of a sample of the deposited sample. The sample will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification. Furthermore, the following viability statement is provided under 37 C.F.R. § 1.807(b): the sample is deposited at the Institute for Fermentation in Osaka, Japan, located at 17-85, Juso-honmachi 2-chome, Yodogawa-ku, Osaka 532-8686, Japan; the depositors are the present Applicants whose names and addresses are of record; the deposit/accession number is IFO30601 or NBRC30601.

Applicants also submit that the strain IFO30601 has been deposited with the Institute for Fermentation, Osaka (IFO). Organisms on deposit at the IFO were transferred to the NITE Biological Resource Center (NBRC) which distributes and grants access to the strains. The deposit number of IFO30601 is the same as the NBRC deposit access number. That is, the deposit number at NBRC is NBRC30601. Provided herewith as Exhibit A are copies corresponding to the web pages of the IFO website showing the status of the deposit and how it may be ordered.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-5, 9 and 10 stand rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. (See, Office Action, at pages 7-9). Claims 1-5, 9 and 10 have been cancelled herein in favor of new claims 12-20, thus obviating the rejection as to these claims. However, Applicants provide the following remarks concerning the rejection to the degree that the bases for the rejections may also apply to new claims 12-20.

The Examiner states that the term "phenol oxidase" is indefinite. The Examiner states that there are many different types of phenol oxidases which operate on diverse populations of substrates. The Examiner further states that the phrase, "28 kDa (calculated by SDS-PAGE)" is unclear. That is, the Examiner is not sure whether Applicants intend to claim a holoenzyme which has a molecular weight of 72 kDa before or after gel filtration or which has an additional subunit of 28 kDa. The Examiner also states that the phrase "optimum pH" is indefinite. The Examiner states that the claims do not require any enzyme activity or how it should be measured, or under which conditions. Finally, the Examiner points out that some terms in claims 4 and 5 lack antecedent basis.

Although Applicants do not believe the claims are indefinite, to expedite prosecution, new claims 12-20 are presented which are believed to address all of the bases for the Examiner's rejections. That is, independent claim 12 recites an enzyme that has a specific activity of catalyzing the oxidation of N,N-dimethyl-para-phenylenediamine, ortho-aminophenol, 2,6-dimethoxyphenol, 1,3-dihydroxynaphthol, and 4-hydroxyindole, the polymerization of alkali extract of lignin at a pH of between 5.0 to 7.0.

New claim 12 also combines the limitations of previous claim 2 (now cancelled) and further defines the enzyme by reciting various molecular weight and size parameters, as determined by SDS-PAGE and several specific limitations regarding maintenance of enzyme activity under certain conditions.

It is believed that these new claims 12-20 adequately address the Examiner's concerns because they no longer recite terms lacking antecedent basis, clearly describe molecular weights and ranges based on well-known standard procedures and because the claims recite a specific enzymatic activity (claim 12).

Rejections Under 35 U.S.C. § 102(b)

Nishizawa et al.

Claims 1-5 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Nishizawa et al., *Myoscience*, 44:19-23, 2003 (hereinafter, "Nishizawa et al."). (See, Office Action, at page 9). Claims 1-5 have been cancelled herein in favor of new claims 12-20, thus obviating the rejection as to these claims. However, Applicants provide the following remarks concerning the rejection to the degree that the bases for the rejections may also apply to new claims 12-20.

The Examiner states that Nishizawa et al. disclose the organism *F. velutipes* strain IFO 30601 which would inherently produce and possess the same phenol oxidase as recited in the instant claims. However, Nishizawa et al. disclose enzyme activity of an esterase, which is not the same activity as possessed by the presently claimed enzyme.

Furthermore, claims 12-20 require that the enzyme be isolated. Nishizawa et al. do not disclose an isolated enzyme as presently claimed. Thus, Nishizawa et al. cannot anticipate the

presently claimed invention. Anticipation requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (*See, In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949 (Fed. Cir. 1990), quoting *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)).

Schanel, Lan and Lee

Claims 1-4 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Schanel, *Biol. Plant.*, Acad. Sci. Bohemoslov. 1966, 8(4):292-298 (abstract only, hereinafter, "Schanel") and Lan, and Lee. (*See*, Office Action, at page 10). Claims 1-4 have been cancelled herein in favor of new claims 12-20, thus obviating the rejection as to these claims. However, Applicants provide the following remarks concerning the rejection to the degree that the bases for the rejections may also apply to new claims 12-20.

The Examiner states that Schanel and Lan disclose a phenol oxidase produced by *F. velutipes*. The Examiner further states that Lee discloses an *F. velutipes* laccase having a pH stability in the range of pH 5.0 to pH 7.0 at around 40 °C.

However, none of the cited references disclose an isolated enzyme, as presently claimed. Furthermore, Applicants provide attached hereto the SAITO Declaration under 37 C.F.R. § 1.132 which shows that the enzyme of Lee is not the same as the presently claimed enzyme. The SAITO Declaration shows that the enzyme of Lee has a K_m of 28 mM whereas the presently claimed enzyme has a K_m of 0.33 mM. This is a difference of 1,000 fold in the physical properties of the enzyme of the presently claimed invention as compared to the enzyme disclosed in the cited reference.

Thus, Schanel, Lan and Lee cannot anticipate the presently claimed invention because they do not disclose all of the limitations of the presently claimed invention. (*See, In re Robertson*, 169 F.3d at 745).

Lindeberg

Claims 1-3 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Lindberg, *G. Physiologica Plantarum*, 1:196-205, 1948 (abstract, hereinafter, "Lindberg"). (*See, Office Action*, at page 10). Claims 1-3 have been cancelled herein in favor of new claims 12-20, thus obviating the rejection as to these claims. However, Applicants provide the following remarks concerning the rejection to the degree that the bases for the rejections may also apply to new claims 12-20.

The Examiner states that Lindberg discloses a phenol oxidase produced by the organism *F. velutipes* which would intrinsically have the properties claimed.

However, claims 12-20 require that the enzyme be isolated. Lindberg does not disclose an isolated enzyme as presently claimed. Thus, Lindberg cannot anticipate the presently claimed invention. (*See, In re Robertson*, 169 F.3d at 745).

Kiiskinen et al.

Claims 1, 9 and 10 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Kiiskinen et al., *Appl. Microbiol. Biotechnol.*, 59:198-204, 2002 (hereinafter, "Kiiskinen et al."). (*See, Office Action*, at pages 10-11). Claims 1, 9 and 10 have been cancelled herein in favor of new claims 12-20, thus obviating the rejection as to these claims. However, Applicants provide

the following remarks concerning the rejection to the degree that the bases for the rejections may also apply to new claims 12-20.

The Examiner states that Kiiskinen et al. disclose a phenol oxidase having a broad pH optimum and reacting with 2,6-dimethoxyphenol.

However, claims 12-20 require that the enzyme be isolated. The enzyme of Kiiskinen et al. is not isolated, as is the presently claimed enzyme. Furthermore, claim 12 corresponds to a combination of the limitations of claims 1 and 2. Since claim 2 is not anticipated by the disclosure of Kiiskinen et al., new claim 12 also cannot be anticipated by Kiiskinen et al. Thus, Kiiskinen et al. cannot anticipate the presently claimed invention. (*See, In re Robertson*, 169 F.3d at 745).

Echigo et al.

Claim 1 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Echigo et al., JP 09-206071 A (hereinafter, "Echigo et al."). (*See, Office Action*, at page 11). Claim 1 has been cancelled herein in favor of new claims 12-20, thus obviating the rejection as to claim 1. However, Applicants provide the following remarks concerning the rejection to the degree that the bases for the rejections may also apply to new claims 12-20.

The Examiner states that Echigo et al. disclose a phenol oxidase having a pH optimum of approximately 7.0.

However, claims 12-20 require that the enzyme be isolated. The enzyme of Echigo et al. is not isolated. Furthermore, claim 12 corresponds to a combination of the limitations of claims 1 and 2. Since claim 2 is not anticipated by the disclosure of Echigo et al., new claim 12 also

cannot be anticipated by Echigo et al. Therefore, Echigo et al. do not disclose an isolated enzyme as presently claimed. Thus, Echigo et al. cannot anticipate the presently claimed invention. (See, *In re Robertson*, 169 F.3d at 745).

Rejections Under 35 U.S.C. § 103(a)

Palmieri et al. & Farrell

Claims 1, 9 and 10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over Palmieri et al., *Appl. Microbiol. Biotechnol.*, 39:632-636, 1993 (hereinafter, "Palmieri et al.") in light of Farrell, *Phil. Trans. R. Soc. Lond. A.*, 321:549-553, 1987 (hereinafter, "Farrell"). (See, Office Action, at page 11-13). Claims 1, 9 and 10 have been cancelled herein in favor of new claims 12-20, thus obviating the rejection as to these claims. However, Applicants provide the following remarks concerning the rejection to the degree that the bases for the rejections may also apply to new claims 12-20.

The Examiner states that Palmieri et al. disclose or suggest a phenol oxidase from basidiomycete having a pH optimum of between 5.0 and 7.0 and that the oxidase provides an activity which decolors dye compositions. The Examiner further states that Farrell disclose or suggest use in industry of lignin-transforming fungal enzymes which can reduce the chromophoric groups in lignin bleaching, reduce brightness inversion and decolorization. However, the Examiner admits the references do not disclose or suggest a composition which is identical to the presently claimed composition.

Applicants reiterate statements made above concerning new claim 12. That is, new claim 12 is in fact a combination of the limitations of previously presented claims 1 and 2. Since claim

2 is not rejected as being obvious in light of the cited references, new claim 12 is likewise believed to be non-obvious. Furthermore, all claims depending therefrom are likewise believed to be non-obvious since no independent reasoning is provided for the rejection of dependent claims 9 and 10.

Kleen et al., U.S. Patent Application Publication No. 2006/0277694

Claims 1, 9 and 10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over Kleen et al., U.S. Patent Application Publication No. 2006/0277694 (hereinafter, "Kleen et al.") as evidenced by DE 103.59.577.0. (See, Office Action, at pages 13-14). Claims 1, 9 and 10 have been cancelled herein in favor of new claims 12-20, thus obviating the rejection as to these claims. However, Applicants provide the following remarks concerning the rejection to the degree that the bases for the rejections may also apply to new claims 12-20.

The Examiner states that Kleen et al. disclose or suggest a dye composition comprising a phenol oxidase enzyme from various organisms which are capable of oxidizing a dye including *o*-aminophenol and 4-hydroxyindole. The Examiner admits that Kleen et al. do not disclose or suggest the specific combination of a neutral phenol oxidase with the dye substrates. However, the Examiner states that Kleen et al. disclose enzymes which directly oxidize the dye precursors.

Applicants reiterate statements made above concerning new claim 12. That is, new claim 12 is in fact a combination of the limitations of previously presented claims 1 and 2. Since claim 2 is not rejected as being obvious in light of the cited references, new claim 12 is likewise believed to be non-obvious. Furthermore, all claims depending therefrom are likewise believed

to be non-obvious since no independent reasoning is provided for the rejection of dependent claims 9 and 10.

Rejections Under the Obviousness-Type Double Patenting Doctrine

Claims 1-5, 9 and 10 stand provisionally rejected under the judicially created doctrine against obviousness-type double patenting as being unpatentable by U.S. Patent No. 7,135,184. (*See*, Office Action, at page 15). Although claims 1-5, 9 and 10 have been cancelled, Applicants submit herewith a Terminal Disclaimer with respect to the '184 patent for the presently pending claims. Applicants believe the Terminal Disclaimer adequately addresses the obviousness-type double patenting rejection and respectfully request reconsideration and withdrawal of the rejection.


CONCLUSION

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: January 4, 2008

Respectfully submitted,

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Attachments: Drawing of Figure 16 (1 sheet)
Exhibit A: copies corresponding to the web pages of the IFO website (10 pages)
Declaration under 37 C.F.R. § 1.132 (4 pages)
Terminal Disclaimer (1 page)